PUBLIC NOTICE: DEVIATION TO THE STANDARD PATENT RIGHTS CLAUSE (FAR 52.227-11 PATENT RIGHTS - RETENTION BY THE CONTRACTOR (SHORT FORM)), IN A CONTRACT TO BE AWARDED UNDER THE NIH ROADMAP: "MOLECULAR LIBRARIES SMALL MOLECULE REPOSITORY"

RELEASE DATE: January 30, 2004

RFP RELEASE DATE: DECEMBER 31, 2003

NOTICE: NOT-RM-04-008

National Institutes of Health (NIH)

COMMENTS/ALTERNATIVE PLAN RECEIPT DATE: MARCH 2, 2004

DESCRIPTION

The NIMH is seeking public comments (or alternative plans) regarding potential use of a deviation to the standard patent rights clause (FAR 52.227-11 Patent Rights - Retention by the Contractor (Short Form), in a contract to be awarded under the NIH Roadmap: "Molecular Libraries Small Molecule Repository". The proposed clause is included in full text below, and also in the solicitation for this contract (NIMH-04-DB-0001), which can be accessed at: http://www.nimh.nih.gov/grants/indexcon.cfm#RequestforProposal and in the FedBizOpps at: http://vsearch1.eps.gov/servlet/SearchServlet.

If a Determination of Exceptional Circumstances (DEC) were implemented, this clause deviation would serve to protect the pre-existing and future patent rights of suppliers of proprietary materials for synthesis or inclusion in the compound collection/repository. The proposed clause deviation only applies to discoveries resulting from routine synthesis activities and repository activities involving the use of proprietary materials (compounds and procedures). Discoveries resulting from research activities pertaining to the development or modification of chemical synthesis procedures, process development, or other unanticipated discoveries developed by the contractor without the use of proprietary materials will be covered by the standard Patent Rights Clause (FAR 52.227-11, Patent Rights - Retention by the Contractor (Short Form) (June 1997). Furthermore, the Contractor will have the right to ask for greater rights, as defined in the clause, if the supplier of the proprietary compound is not interested in the subject invention.

Potential offerors and other interested parties are invited to submit comments herein or provide "alternative plans" when responding to the solicitation for this contract (http://www.nimh.nih.gov/grants/indexcon.cfm#RequestforProposal), which would serve to meet the objectives/goals of this Program without the use of this deviation. All plans and comments will be considered and discussed with interested parties.

Any comments or alternative plans regarding this clause should be submitted, in writing, by March 2, 2004, to Mr. Bruce Anderson, Contracting Officer, Contract Management

Branch, NIMH, NIH, 6001 Executive Blvd., Rm. 8154 (MSC 9661), Bethesda, MD 20892 (for Fed Ex, UPS etc. use Rockville, MD 20852); Voice: (301) 443-2234; Fax: (301) 443-0501; E-Mail: ba9i@nih.gov. See solicitation for instructions on submission of an "alternative plan" with a proposal.

The following Statement of Facts provides more detail into the potential use of a deviated patent rights clause:

Statement of Facts

The primary goal of the Molecular Libraries initiative is to improve public health by stimulating the discovery, development, and commercialization of new research tools and potential therapeutic compounds for the treatment of a variety of disorders and the validation of new targets for drug therapy. We believe the synthesis and repository activities of this contract may constitute an exceptional circumstance where the imposition of a FAR deviation, through a Determination of Exceptional Circumstances (DEC), would further the achievement of the programmatic goals and meet the objectives of 35 U.S.C. 200. Historically, the NIMH has obtained the approval of DECs in similar contract programs where proprietary materials are involved.

To meet the goals and objectives of the Molecular Libraries Small Molecule Repository, this contract will need to acquire and maintain a library of hundreds of thousands of diverse small molecules, which will become a major resource to investigators for further evaluation in a wide variety of assays of biological activity. The small molecules collected in this repository will be arrayed and sent to screening centers (i.e., grantees, which are not part of this contract) or investigators, to be evaluated and screened for a large number of possible new activities and applications. Screening will enhance the identification of small molecules that are useful as research tools (e.g., probes to alter the function of novel proteins or molecular imaging probes) or as starting points for the development of novel compounds with therapeutic potential. The contractor shall maintain an appropriate quantity of each compound by either repurchasing additional quantities, or through synthesis efforts. Under this contract, both proprietary and non-proprietary materials will be provided directly by the compound suppliers (or through NIH) to the contractor for inclusion in the compound collection/repository. It is anticipated that some of the most unique and promising compounds with the most interesting biological activities will be proprietary. Therefore, in order for this program to succeed, it will be essential to obtain a sufficient flow of proprietary materials.

Our previous experience and discussions with compound suppliers (i.e., investigators at academic institutions, biotechnology companies, and pharmaceutical companies) have shown that they will not submit their proprietary materials without complete assurance that their intellectual property rights will be protected, such as that which could be provided through a DEC.

Through discussions with these organizations it was determined that, except for the

protection offered by this clause, the NIH would have no other method to gain access to some of these promising compounds; this would result in a less effective and less diverse and unique compound collection. As many of the compounds with the most interesting activity will be proprietary, having an insufficient number of these compounds submitted for inclusion in the repository would inhibit the discovery of promising new leads for further development as potential research tools or therapeutics. This would not appear to appropriately support the objectives of 35 U.S.C. 200, et. seq., or benefit the public health under this program.

Pharmaceutical and biotechnology companies are highly unlikely to invest in areas such as the development of research compounds to be used as research tools, imaging probes, or as therapeutics for rare or 'orphan' diseases because of cost-restraints and low potential returns. Therefore, this program will fill a critical need by supporting and stimulating the development of much-needed research tools and potential therapeutics that might not otherwise be developed. It is expected that many investigators who use the compound collection will go on to further develop these compounds into much-needed agents and therapeutics to further research and benefit the public health.

We recognize the scientific expertise of the contractors and the importance of the Bayh-Dole Act in protecting the intellectual property rights of contractors. While Bayh-Dole provides incentives for the commercialization of Government supported research and development by allowing contractors to retain rights to inventions, the Act also permits an exception to this provision under exceptional circumstances. In this instance, we believe that restriction or elimination of the contractor's right to retain title to subject inventions, in a narrow field, may be needed to further the programmatic goals of research and development in order to benefit public health.

If adopted, use of the proposed restricted Patent Rights clause has been narrowly tailored to apply only to subject inventions using proprietary materials obtained and evaluated under these contracts, and not to subject inventions outside the scope of the deviated patent rights clause. The Contractor will have the right to ask for greater rights, as defined in the clause, if the supplier of the proprietary materials is not interested in licensing or pursuing the invention. Furthermore, even if a DEC were implemented, rights to subject inventions made without the use of proprietary materials would remain with the contractor, and will be subject to the standard clause at FAR 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1997).

Based on previous experience with similar programs, we have discussed and considered approaches other than the use of a DEC for acquiring and evaluating proprietary materials, but we are not currently aware of any viable alternatives that would adequately address the concerns noted above.

[End of Statement of Facts]

Authority to use the following clause may be sought for the contract entitled "Molecular Libraries Small Molecule Repository":

52.227-11 Patent Rights (Deviation)

This clause deviation applies to discoveries resulting from routine synthesis or repository activities involving the use of proprietary materials (compounds and procedures). Discoveries resulting from research activities pertaining to the development of new assays or the development or modification of chemical synthesis procedures, process development or other unanticipated discoveries developed by the contractor without the use of proprietary materials will be covered by the standard Patent Rights Clause (FAR 52.227-11, Patent Rights – Retention by the Contractor (Short Form) (June 1997)

(a) Definitions. (1) "Invention" means any invention or discovery, which is or may be patentable or otherwise protectable under title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, et, seq.)

(2) "Made" when used in relation to any invention, means the conception or first actual reduction to practice of such invention.

(3) "Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statue.

(4) "Practical application" means to manufacture, in the case of a composition of matter or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(5)"Small business firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) "Subject Invention" for the purpose of this clause, means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in Section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(7) "Compound Suppliers" means any entities or organizations that make available to NIMH a composition of matter or product, patented or unpatented.

(8) “NIMH” means the National Institute of Mental Health of the National Institutes of Health (NIH).

(9) “NIH” means the National Institutes of Health.

(b) Allocation of principal rights. (1) Retention of pre-existing rights.

Compound Suppliers shall retain all pre-existing rights to those compounds in which the compound supplier has a proprietary interest.

(2) Assignment to the NIH or compound supplier. The contractor agrees to assign to the NIH or to a Compound Supplier designated by NIMH the entire right, title, and interest throughout the world to each subject invention except to the extent that rights are retained by the contractor under subparagraph (b)(3) of this clause and subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the United States Government to practice or have practiced the subject invention for or on behalf of the United States throughout the world.

(3) Greater Rights Determinations. The contractor, or an employee-inventor after consultation by the NIMH with the contractor, may request greater rights to an identified subject invention of the contract in accordance with the procedures of FAR paragraph 27.304-1(b) and FAR paragraph 27.304-1(c) (in the case of an employee-inventor) subject to the considerations set forth below. The NIMH will grant greater rights if the supplier is not interested in developing the invention. In addition to the considerations set forth in paragraph 27.304-1(b), NIMH will consider whether granting the requested greater rights will interfere with rights of the Government or any Compound Supplier or otherwise impede the ability of the Government or the Compound Supplier to develop and commercialize new compositions of matter, compounds, product designs, dosage forms, therapies, technologies or other approaches for the treatment of mental disorders in a rapid, efficient, and cost-effective manner. A request for a determination of whether the contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the NIMH Contracting Officer at the time of the first disclosure of the invention pursuant to subparagraph (c)(1) below, or not later than eight (8) months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13, and to any reservations and conditions deemed to be appropriate by NIMH such as the requirement to assign or exclusively license the rights to subject inventions to the Compound supplier. A determination by NIMH denying a request by the contractor for greater rights in a subject invention may be appealed within 30 days of the date the contractor is notified of the determination to an agency official at a level above the individual who made the determination. If greater rights are granted, the contractor must file a patent application on the invention. Upon request, the contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any subject invention in any country for which the contractor has retained title.

Upon request, the contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) Invention disclosure by contractor. The contractor will disclose each subject invention to the NIMH Contracting Officer as provided in paragraph (j) within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the NIMH Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(d) Contractor action to protect the Government's interest. (1) The contractor agrees to execute or to have executed and promptly deliver to the NIH all instruments necessary to – (i) Establish or confirm the rights the Government has throughout the world in subject inventions pursuant to paragraph b.2. above, and (ii) Convey title to the NIH or to a Compound Supplier when requested under paragraph b.2. of this clause and to enable the NIH or a Compound supplier to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and non technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's right or a Compound Supplier's right in the subject inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars. The contractor will notify the NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response period required by the relevant patent office.

(3) The contractor agrees to include, within the specification of any United States patent application it files and any patent issuing thereon covering a subject invention the following statement, "This invention was made with Government support under (identify

the contract) awarded by the National Institute of Mental Health. The Government has certain rights in the invention."

(4) The contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all subject inventions or stating that there were none.

(e) Subcontracts. (1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental, or research work. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's subject inventions.

(2) In the case of subcontracts, at any tier, NIH, the subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and NIH with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13 which is incorporated by reference in paragraph b.3 of this clause.

(f) Reporting on utilization of subject inventions in the event greater rights are granted to the contractor. The contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees when the NIH has granted a request under subparagraph b.3. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the NIH in connection with any march-in proceeding undertaken by the NIH in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the NIH agrees it will not disclose such information to persons outside the Government without permission of the contractor.

(g) Preference for United States industry in the event greater rights are granted to the contractor. Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the NIH upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights in the event greater rights are granted to the contractor. The contractor agrees that, with respect to any subject invention in which it has acquired title through the exercise of the rights specified in subparagraph (b)(3), the NIH has the right in accordance with the procedures in FAR paragraph 27.304-1 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the NIH has the right to grant such a license itself if the NIH determines that—

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) Such action is necessary because the agreement required by paragraph (g) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(i) Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the contractor. If the contractor is a nonprofit organization, it agrees that—

(1) Rights to a subject invention in the United States may not be assigned without the approval of the NIH, except where such assignment is made to an organization which has as one of its primary functions the management of inventions; provided, that such assignee will be subject to the same provisions as the contractor;

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the NIH deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e);

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses, (including payments to inventors) incidental to the administration of subject inventions will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms, and that it ill give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has plan or proposal for marketing the invention which, if executed,

is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary of Commerce may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the contractor could take reasonable steps to more effectively implement the requirements of this subparagraph.

(j) Communications. All invention disclosures and requests for greater rights shall be sent to the NIMH Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications should be sent to the Office of Extramural Inventions and Technology Resources Branch, OPERA, National Institutes of Health, Rockledge, II, 6701 Rockledge Drive, Room 3190, MSC 7750, Bethesda, MD 20892-7750

---

[Return to Volume Index]

[Return to NIH Guide Main Index]

---